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Washington, D.C. 20231 APPLICATION NUMBER FILING DATE FIRST NAMED APPLICANT 08/977,862 11/25/97 LAWRENCE GH-30170 EXAMINER HM12/0510 RATNER AND PRESTIA PAPER NUMBER SUITE 301 ONE WESTLAKES BERWYN 1645 PO BOX 980 VALLEY FORGE PA 19482-0980 DATE MAILED: 05/10/99 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS OFFICE ACTION SUMMARY This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213. A shortened statutory period for response to this action is set to expire month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Disposition of Claims Çlaim(s) is/are pending in the application. Of the above, claim(s is/are withdrawn from consideration. Ælaim(s) is/are allowed. Claim(s) is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction or election requirement. **Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on is/are objected to by the Examiner. The proposed drawing correction, filed on _ _is 🔲 approved 🔲 disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). ☑ All , Some* None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 17.2(a)). *Certified copies not received: Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) Notice of Reference Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). ☐ Interview Summary, PTO-413 Notice of Draftperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found

in a prior Office action.

Any objections or rejections made in a previous Office Action that are not herein 2.

reinstated have been withdrawn.

3. Applicant's election of Group I, claims 1-5 and 23-24, in Paper No. 9, filed 12/31/98, is

acknowledged. Because applicant did not distinctly and specifically point out the supposed errors

in the restriction requirement, the election has been treated as an election without traverse (MPEP

§ 818.03(a)).

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention for reasons of record and the following. The specification on page 18, line 26 to

page 19, line 2, describes several methods to compute sequence identity. However, the claims are

indefinite because it is not clear which method and what parameters within that method are being

used, so the metes and bounds of the claims are indeterminate because different methods will

produce variable sequence identity percentages.

Applicant's arguments filed 12/31/98 have been fully considered but they are not

persuasive because Applicant argues that "said identity being calculated using FASTA wherein

the two sequences are aligned so that highest order match is obtained" overcomes the rejection

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of record. The algorithm to be employed is a limitation of the instant claims, and the parameters are sufficiently definite in recitation of "maximally aligned so that the highest order match...is obtained." The Examiner respectfully disagrees because "maximally aligned" is not recited in the claims. However, even if such a phrase were recited, the instant claims are still indefinite because the metes and bounds cannot be determined for the following reason. The parameters the artisan sets for any computer program will determine how "high" the "highest" order match that can be obtained will be. The parameters or variables that are given fixed values by the computer user will be critically important in determining the numerical value "match" between any two sequences, as certain parameters might consider conservative substitutions to be a match or a partial match, gaps between sequences may be assessed a penalty or not assigned a penalty, the length and number of gaps between two sequences may affect the numerical value, etc. Given that the highest order match will critically change with the parameters or variables used, the fixed percentage value recited in the claims becomes uncertain because what is encompassed by the claims cannot be recognized by the artisan unless those parameters or variables are fixed and known. Given non-fixed values, the artisan cannot determine if a sequence meets the limitations of the claims or not; even the Examiner is unaware of how much variability over a reference sequence a maximally set highest order match FASTA can make if all parameters and variables are set to their highest fixed value (An integer? A rational number? Infinity?).

5. Claims 5 and 24 are in condition for allowance.

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6. Claim 23 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 24. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

"A polypeptide which has" and "polypeptide comprising" both use open language so they appear to have identical scope. Amending claim 24 to "a polypeptide consisting of" would obviate the grounds of this objection.

- 7. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).
- 8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Thursday from 0730 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SC

Stephen Gucker

May 4, 1999

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